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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,648	01/20/2004	Patrick S. Pevoto	30368.5	5282

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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT PAPER NUMBER

3736

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/762,648	Applicant(s) PEVOTO, PATRICK S.	
	Examiner Charles A. Marmor, II	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed October 7, 2004. The Examiner acknowledges the amendments to the specification; the amendments to claims 1 and 3-7; the cancellation of claim 2; and the addition of new claim 8. Claims 1 and 3-8 are currently pending.

Terminal Disclaimer

2. The terminal disclaimer filed on October 7, 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,702,759 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 3-5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Widlund et al. ('381) in view of Sheldon ('459).

Widlund et al. teach a tampon device that collects cells and vaginal fluids. The device includes a shaped absorbent member 1 adapted for intra-vaginal insertion; a gauze (textured mesh) sheath 3 that is molded onto the absorbent member such that the sheath covers the absorbent member; and a means for retrieving 2 the absorbent member. The mesh sheath has a

plurality of evenly spaced openings formed therein. The texture of the mesh captures cells residing in vaginal fluids and passes the cells and fluid to the absorbent member. The sheath also retains the shape of the absorbent member so that the absorbent member does not lose fibers or cling to the mucus membrane of the vagina. Widlund et al. teaches all of the limitations of the claims except that the cell collecting device includes an intra-vaginal insertion member and means for expelling the absorbent member from the insertion member, i.e. a telescoping tube.

Sheldon teaches a telescoping applicator tube (Fig. 1) for applying a sampling or collection device intra-vaginally. The telescoping applicator tube includes an insertion member 1 and a means for expelling an absorbent member from the insertion member 2. The applicator tube protects the sampling or collection device from contamination and maintains the integrity of the device during insertion.

It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to use a an insertion member and means for expelling an absorbent member from the insertion member similar to that of Sheldon to apply a tampon device similar to that of Widlund et al. in order to protect the sampling tampon device from contamination and to maintain the integrity of the device during insertion.

5. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Widlund et al. ('381) in view of Sheldon ('459), as applied to claim 1 above, and further in view of Buck et al. ('481). Widlund et al. and Sheldon, as discussed above, teach all of the limitations of the claims except that the cell collecting device is packaged in a single container to form a kit. Buck et al. teach a kit for self-administered intra-vaginal cell collection including cell collection

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means, a fixative container, shipping means, instructions, and mailing labels. It would have been obvious, in view of Buck et al., to use such a kit for the tampon, telescoping applicator tube, and fixative container of Widlund et al. as modified by Sheldon in order to make the collection of sampling and collecting materials conveniently available to a consumer for over-the counter purchase for use in the privacy of the home.

Response to Arguments

6. Applicant's arguments with respect to claims 1 and 3-8 have been considered but are moot in view of the new ground(s) of rejection. Applicant contends that Bucalo, Sheldon and Buck all fail to teach or suggest a textured flexible mesh covering an absorbent member. This argument is moot in view of the new grounds of rejection citing Widlund et al. set forth hereinabove. Widlund et al. teach a sampling device including a textured mesh covering an absorbent member and attached to a retrieval string.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Sheldon teaches a telescoping applicator tube for applying a tampon-type sampling or collection device intra-vaginally. It is well known in the art to use a telescoping applicator tube similar to that of Sheldon to insert any tampon-type sampling or

collection device intravaginally. Buck et al. teach a kit for self-administered intra-vaginal devices illustrating that it is well known in the art to place all apparatus that might be needed for an intravaginal procedure into a container in order to form a kit that is conveniently available to a consumer for over-the counter purchase and for use in the privacy of the home.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Moehrle ('180) teaches an intravaginal collection device that is stored in a container in order to form a kit.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

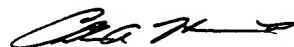
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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December 20, 2004